Massachusetts Department of Public Health (MDPH)
Division of Epidemiology and Immunization

MDPH requests that health-care providers be alert for possible cases of intussusception in infants following administration of rotavirus vaccine.

- As with all vaccines, please inform parents of children receiving rotavirus vaccine of the risks of the vaccine, and instruct them to contact you if their child experiences stomach pain, vomiting, diarrhea, blood in their stool or change in their bowel movements after vaccination.
- Please immediately report any possible cases of intussusception (or any other serious adverse event) following vaccination to the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967 or reporting on line to www.vaers.hhs.gov.
- MDPH would also like to know about any cases of intussusception following rotavirus vaccination in Massachusetts. After reporting to VAERS, please contact MDPH Immunization Program at 617-983-6800 to report any suspected or confirmed case.

FDA Public Health Notification

Information on RotaTeq and Intussusception

February 13, 2007

The Food and Drug Administration (FDA) is notifying health care providers and consumers about 28 post-marketing reports of intussusception following administration of Rotavirus, Live, Oral, Pentavalent vaccine (trade name RotaTeq), manufactured by Merck and Co., Inc. Intussusception is a serious and potentially life-threatening condition that occurs when the intestine gets blocked or twisted. One portion of the intestine telescopes into a nearby portion, causing the intestinal obstruction. The most common site is where the small intestine joins the large intestine.

Intussusception can occur spontaneously in the absence of vaccination. Of the reported 28 cases of intussusception, the number that may have been caused by the vaccine, or occurred by coincidence, is unknown.

FDA is issuing this notification both to encourage the reporting of any additional cases of intussusception that may have occurred or occur in the future after administration of RotaTeq, and to remind people that intussusception is a potential complication of RotaTeq,.

Current Status

Approximately 3.5 million doses of RotaTeq have been distributed in the United States through February 1, 2007. Not all of these doses have been administered. Since its licensure on February 3, 2006 until January 31, 2007, 28 cases of intussusception have been reported in the U.S. in infants who received RotaTeq. These cases have been reported to the Vaccine Adverse Event Reporting System (VAERS). The reported 28 cases occurred after dose 1, dose 2 and dose 3. Approximately half of the cases occurred 1 to 21 days after vaccination, with a range of 0 to 73 days. Sixteen of the 28 infants with intussusception required hospitalization and surgery on their intestine. The remaining 12 infants had reduction of the intussusception by contrast or air enema. No deaths due to intussusception were reported.

The number of intussusception cases reported to date after RotaTeq administration does not exceed the number expected based on background rates of 18-43 per 100,000 per year for an unvaccinated population of children ages 6 to 35 weeks *(CDC, unpublished data)*.

History

RotaTeq is indicated for the prevention of rotavirus gastroenteritis and was studied pre-licensure in a clinical trial population of approximately 70,000 infants (35,000 infants received RotaTeq and 35,000 received placebo), and no significant increased risk of intussusception was found (e.g., six cases were seen in RotaTeq recipients vs. five in placebo recipients). However, a different rotavirus vaccine, which is no longer marketed, may have increased the incidence of intussusception following its use. Therefore, to further evaluate whether, in the general population, RotaTeq could be associated with increased rates of intussusception or other serious adverse events, not only is VAERS data being evaluated continually, but Merck is conducting a post-marketing study of approximately 44,000 infants, and the CDC Vaccine Safety Data Link is conducting a post-marketing study of approximately 90,000 infants.

Recommendations

Because vaccine adverse events are not always reported to FDA, there may be additional cases of intussusception following vaccination of which we are unaware of at this time. This information is important in helping FDA and CDC assess whether RotaTeq may be associated with an increased risk of intussusception and, if so, to what degree. Therefore, we are encouraging all health care professionals, and any other individuals, to report any cases of intussusception or other serious events that may be associated with the use of RotaTeq to VAERS, which is maintained by FDA and CDC. For a copy of the vaccine reporting form, call 1-800-822-7967 or report on line to www.vaers.hhs.gov

Parents should contact their child's doctor immediately if the child has stomach pain, vomiting, diarrhea, blood in their stool or change in their bowel movements, as these may be signs of intussusception. It is important to contact the child's doctor if there are any questions or if the child has any of these symptoms at any time after vaccination, even if it has been several weeks since the last vaccine dose.

FDA and the CDC will continue close monitoring of intussusception and other adverse events associated with RotaTeq. The RotaTeq label and Patient Product Information have been updated to include post-marketing reports of intussusception. The dosage and administration schedule remains unchanged in the label.

RotaTeq Label (PDF - 161 KB)
Patient Product Information (PDF - 69 KB)

Getting More Information

Additional questions may be directed to FDA's Center for Biologics Evaluation and Research at 1-800-835-4709 or by e-mail at octma@cber.fda.gov.

The intent of this public health notification from the Center for Biologics Evaluation and Research is to provide an update of safety information to health care providers as new information becomes available and our understanding of an issue is still evolving. We will revise this notice as new information merits and so encourage you to check this site for updates.

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